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COVID-19

Evaluating and Testing Persons for Coronavirus Disease 2019Centers for Disease Control and Prevention Adapted Guidelines

https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html

Criteria to Guide Evaluation and Laboratory Testing for COVID-19

All health care providers, facilities, and entities that offer testing shall make that testing available to people meeting testing criteria without regard to that person's ability to pay, type of health insurance, or participation in any particular provider network. Health care providers shall provide testing free of charge, including eliminating any cost sharing, co-payments or other direct-to-consumer costs.

The Delaware Division of Public Health (DPH) requires that all commercial labs report all testing for SARS- CoV-2 immediately to DPH via fax to 302-223-1540, email to reportdisease@delaware.gov, or 24-hour Office of Infectious Disease Epidemiology phone line at 1-888-295-5156. Further, all results should be shared electronically through the Delaware Electronic Reporting Surveillance System (DERSS) immediately.

Clinicians considering testing of persons with possible COVID-19 should continue to work with DPH to coordinate testing through public health laboratories or use COVID- 19 diagnostic testing authorized by the Food and Drug Administration under an Emergency Use Authorization (EUA) through clinical laboratories. Increasing testing capacity now allows clinicians to consider COVID-19 testing for a wider group of patients, including asymptomatic patients.

Clinicians should use their judgment to determine if a patient should be tested. Asymptomatic infection with SARS-CoV-2, the virus that causes COVID-19, has been identified. Many patients with confirmed COVID-19 have developed fever¹ and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing) but some people may present with other symptoms as well. Other considerations that may guide testing are epidemiologic factors such as the occurrence of local community transmission of COVID-19 in a jurisdiction. Clinicians are encouraged to test for other causes of respiratory illness.

Other considerations that may guide testing are epidemiologic factors such as known exposure to an individual who has tested positive for SARS-CoV-2, and the occurrence of local community transmission or transmission within a specific setting/facility (e.g., nursing homes) of COVID-19. Clinicians are strongly encouraged to test for other causes of respiratory illness, for example



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influenza, in addition to testing for SARS-CoV-2, if appropriate. Another population in which to prioritize testing of minimally symptomatic and even asymptomatic persons are long-term care facility residents, especially in facilities where one or more other residents have been diagnosed with symptomatic or asymptomatic COVID-19.

SARS-CoV-2 can cause asymptomatic, pre-symptomatic, and minimally symptomatic infections, leading to viral shedding that may result in transmission to others who are particularly vulnerable to severe disease and death. Even mild signs and symptoms (e.g., sore throat) of COVID-19 should be evaluated among potentially exposed health care personnel, due to their extensive and close contact² with vulnerable patients in healthcare settings. Additional information is available in CDC's Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease 2019 (COVID-19).

Recommendations for Reporting, Testing and Specimen Collection

Clinicians should immediately implement <u>recommended infection prevention and control</u> <u>practices</u> if a patient is suspected of having COVID-19. They should also notify infection control personnel at their health care facility and DPH if a patient is classified as a Person Under Investigation (PUI) for COVID-19.

Testing may only be performed under the direction and order of an independently licensed medical practitioner (MD/DO, DMD/DDS, PA, or APRN). For the purposes of this guidance, pharmacists are also considered independently licensed medical practitioners and may direct and order testing for COVID-19.

All testing for SARS-CoV-2 should be conducted in consultation with a health care provider. Specimens should be collected as soon as possible once a decision has been made to pursue testing, regardless of the time of symptom onset. The guidance below addresses options for collection of specimens. For initial diagnostic testing for SARS-CoV-2, CDC recommends collecting and testing an upper respiratory specimen. The following are acceptable specimens:

- A nasopharyngeal (NP) specimen collected by a health care professional; or
- An oropharyngeal (OP) specimen collected by a health care professional; or
- A nasal mid-turbinate swab collected by a health care professional or via supervised onsite self-collection (using a flocked tapered swab); or
- An anterior nares (nasal swab) specimen collected by a health care professional or by onsite or home self-collection (using a flocked or spun polyester swab); or



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• Nasopharyngeal wash/aspirate or nasal wash/aspirate (NW) specimen collected by a health care professional.



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Consistent with FDA guidance, the State of Delaware has identified point-of-care lateral flow immunoassays ("rapid tests") as useful diagnostic adjuncts for COVID-19 and subsequently developed guidance for use of these tests. Use of rapid tests is contingent upon implementation in appropriate clinical scenarios. Rapid testing may only be performed in accordance with Division of Public Health guidance on the use of rapid testing: (https://coronavirus.delaware.gov/wp-content/uploads/sites/177/2020/04/RAPID-COVID-19-lgG-lgM-TESTING-GUIDANCE.pdf).

Only tests that have received an Emergency Use Authorization (EUA) from the FDA **OR** that have been independently verified by a CLIA certified laboratory may be used. All testing must be performed in compliance with OSHA and CLIA regulations or if conducted in a clinical laboratory setting, in accordance with standards set forth by the Commission on Office Laboratory Accreditation (COLA).

Race and ethnicity fields must be completed by the ordering provider in all laboratory order requests. All providers must provide each patient tested with educational materials developed by the Division of Public Health.

The ultimate implementation of, the clinical decision making from, and the reporting of COVID-19 testing, are the responsibilities of the licensed practitioner (MD/DO, DMD/DDS, PA, APRN, or pharmacist) who is listed as the ordering practitioner for the testing procedure.

Footnotes

- ¹ Fever may be subjective or confirmed.
- ² For health care personnel, testing may be considered if there has been exposure to a person with suspected COVID-19 without laboratory confirmation. Because of their often extensive and close contact with vulnerable patients in health care settings, even mild signs and symptoms (e.g., sore throat) of COVID-19 should be evaluated among potentially exposed health care personnel. Additionally, DPH recommends routine surveillance testing of health care personnel.